Public Health Association
AUSTRALIA

Public Health Association of Australia submission on the Customs Amendment (Comprehensive and Progressive Agreement for Trans-Pacific Partnership Implementation) Bill 2018 [Provisions], Customs Tariff Amendment (Comprehensive Agreement for Trans-Pacific Implementation) Bill 2018 [Provisions]

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"*The threat of legal action, or even the existence of an ISDS mechanism, can deter governments from implementing public health policies and laws*." – page 8, below

"*MSF remains gravely concerned about the effects that the Trans-Pacific Partnership trade deal will have on access to affordable medicines for millions of people, if it is enacted*." – page 11, below

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The Public Health Association of Australia

Public health includes, but goes beyond the treatment of individuals to encompass health promotion, prevention of disease and disability, recovery and rehabilitation, and disability support. This framework, together with attention to the social, economic and environmental determinants of health, provides particular relevance to, and expertly informs the role of the Public Health Association of Australia (PHAA).

PHAA is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles. PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups.

The PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups the Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

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Health Equity

As outlined in the Public Health Association of Australia's objectives:

> *Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people's health. The health status of all people is impacted by the social, political, and environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease.*

The PHAA notes that:

- Health inequity differs from health inequality. A health inequality arises when two or more groups are compared on some aspect of health and found to differ. Whether this inequality (disparity) is inequitable refers to measurable differences between (or among, or within) groups.
- Health inequity occurs as a result of unfair, unjust social treatment – by governments, organisations and people, resulting in macro politico-economic structures and policies that create living and working conditions that are harmful to health, distribute essential health and other public services unequally and unfairly, preventing some communities and people from participating fully in the cultural, social or community life of society.

Introduction

PHAA welcomes the opportunity to provide input to the Senate Legal and Constitutional Affairs Committee inquiry into the Customs Amendment (Comprehensive Progressive Agreement for Trans-Pacific Partnership Implementation) Bill 2018 [Provisions] and Customs Tariff Amendment (Comprehensive Agreement for Trans-Pacific Implementation) Bill 2018 [Provisions].

During 2018, the PHAA has made submissions to the Senate Foreign Affairs, Defence and Trade Committee on Treaties ("FADT") Inquiry into the proposed Comprehensive and Progressive Agreement for Trans-Pacific Partnership) ("CPA-TPP", also known as TPP-11), and to the Joint Standing Committee on Treaties ("JSCOT") on this subject. This present submission is essentially identical to the FADT and JSCOT submissions. (The original proposed Trans-Pacific Partnership agreement, when the United States was also a potential party, will be referred to as "TPP" in this submission.)

PHAA advocates for the reduction of social and health inequities as an over-arching goal of national policy and recognised as a key measure of our progress as a society. The Australian Government should take this into account in the negotiation of all international treaties. Treaties, along with all public health activities and related government policy should be directed towards reducing social and health inequity nationally as well as internationally.

PHAA believes that Australia's government should adopt a practice that treaties such as CPA-TPP are always accompanied by comprehensive and independent health impact assessments.

Response to the proposed Agreement

PHAA policy on trade agreements and public health

PHAA has a policy on trade agreements and health which can be found here:

http://www.phaa.net.au/advocacy-policy/policies-position-statements#Intnerational%20Health

The policy states that:

1. Trade agreements should not limit or override a Government's ability to legislate and regulate systems and infrastructure that contribute to the health and well-being of its citizens.
2. The ability of governments to develop and implement policy that protects public health needs to be preserved in trade agreements.
3. PHAA advocates a trade regime that ensures ecological sustainability and equity in population health as well as economic development.

The policy also commits to advocating at the national and international levels to promote and protect public health within international trade agreements and limit adverse impacts of trade agreements on human and planetary health in Australia and internationally.

Trade agreements are a significant determinant of health. They can affect many aspects of health care and public health including:[1,2]

- access to affordable medicines;
- the equitable provision and quality of health care services;
- the ability of governments to regulate health damaging products such as tobacco, alcohol and processed foods;

- the nutritional status of populations;
- access to many of the social determinants of health such as employment and income; and
- a nation's ability to protect the natural environment, a fundamental determinant of human health, prosperity and wellbeing.

PHAA is particularly concerned about the emerging trend of trade agreements that aim to extend into areas that have previously been matters for domestic policy making. This includes agreements such as CPA-TPP, to which Australia is now a signatory.

Potential impact of the Agreement on public health

In 2016 we made submissions to the Joint Standing Committee on Treaties and the Senate Foreign Affairs and Trade Committee inquiries highlighting several areas of public health concern regarding the final text of the TPP agreement: (i) investor-state dispute settlement (ISDS), (ii) the potential effects of the intellectual property chapter on access to affordable medicines, (iii) lack of effective environment protection, and (iv) provisions that could act as a deterrent to the introduction of effective health information on alcohol containers. Most of these concerns remain relevant with respect to the CPA-TPP.

The re-negotiation of the CPA-TPP following the withdrawal of the United States has resulted in the suspension of a small number of provisions, presumably pending the re-entry of the US at a later stage. Many of these are in the intellectual property chapter, and include some that would have been problematic in terms of access to affordable medicines. While their suspension is a step in the right direction, these provisions have not been removed, and could be reinstated at a later stage through agreement by the Parties. Some intellectual property provisions that have not been suspended are also likely to cause problems for some countries in terms of access to medicines. The scope of the ISDS mechanism has been narrowed; provisions that apply ISDS to investment agreements and investment authorisations have been suspended in the CPA-TPP. However, these changes have no bearing on the potential for disputes over public health measures. The TPP's annex on labelling of wine and spirits, which may be used to frustrate efforts to introduce evidence-based health warnings, remains unchanged in the CPA-TPP.

Recently, President Trump has signalled that the United States may seek to return to participation in the TPP,[3] however it is clear that this would require the pact to be a "substantially better deal"[4] from a US point of view. In this context, the risk that the suspended intellectual property provisions could be reinstated is very real.

Investor-state Dispute Settlement

Investor-state dispute settlement (ISDS) is a legal mechanism that enables foreign investors to sue governments for monetary compensation over the introduction of policies and laws that they perceive as infringing upon investor rights conferred to them by obligations in an international trade or investment treaty. Policies and laws introduced by Federal, State and Territory or local governments can be subject to disputes. Over the last decade there has been a large increase in investment arbitration cases; from fewer than 10 in 1998 to a total of 568 known cases at the end of 2013[5]. While developing countries have usually been the target for ISDS claims, 2013 marked an increasing share of ISDS cases against developed states. Three quarters of claimants in all known ISDS cases are from the EU and the United States[5].

Foreign investors have used ISDS provisions to sue governments over policies and laws implemented to protect health and the environment. For example, in the late 1990s the US firm Ethyl Corporation launched an ISDS case against the Canadian government over its decision to ban a petroleum additive toxic to human health. The Canadian government paid $13 million to settle with Ethyl Corporation and as part of the settlement was required to reverse its ban[6]. Mexico was required to pay $16.2 million dollars to US waste-

management company Metalclad which sued the government for refusing to grant the firm a construction permit for a toxic waste facility, citing environmental reasons[7].

In 2013, the multinational pharmaceutical company Eli Lilly took the Canadian government to ISDS arbitration, claiming $481 million in compensation over the Canadian court's decision to revoke patents on two medicines that were found to not deliver the promised health benefits. Eli Lilly was not only seeking compensation, but also challenging Canada's domestic intellectual property law, particular its criteria for determining patent validity[8]. This case was decided in favour of the Canadian Government, however this has been described as "at best a temporary, partial, or even pyrrhic victory", as the tribunal "failed to close the door to the possibility that invalidation of intellectual property rights (IPRs) under domestic law could constitute a violation of international investment law in the future". [9] The Canadian Supreme Court subsequently weakened the criteria for determining patent validity, in a decision which observers suggest may be at least partly attributable to the *Eli Lilly v. Canada* ISDS case.[9] Similar policy reversals have been seen in Colombia (which withdrew a compulsory licensing proposal) and Ukraine (which de-registered a generic hepatitis C medicine) after threats of dispute settlement claims by pharmaceutical companies.[9]

Philip Morris's ISDS case against Australia over tobacco plain packaging is another example. In 2011 Philip Morris initiated a dispute with Australia through ISDS provisions in the Hong Kong-Australia Bilateral Investment Treaty. After four years of proceedings, Philip Morris lost its claim in December 2015. While the decision was praised as a win for public health, the case is not a clear test for the potential implications of ISDS for health policymaking. While the text of the decision is still secret and has not been released publicly, the tribunal found that it had no jurisdiction to hear Philip Morris' claim[10]. This was based on the fact that Philip Morris had re-arranged its corporate structure to facilitate its Hong Kong subsidiary interests in the Australian tobacco market after Australia had announced its plain packaging policy[11]. It remains unclear what the outcome would have been had the case not been dismissed on jurisdictional grounds.

Safeguards do not rule out ISDS claims over health and environmental policies

The CPA-TPP text includes some legal safeguards intended to make it less likely that a corporation will make an ISDS claim or to increase the chances that governments will be able to defend an ISDS claim over a legitimate health or environmental policy. However, experts have cautioned that (with the one important exception) these legal safeguards are insufficient to prevent corporations from bringing ISDS claims over legitimate health and environmental policies.[12,13]

The single exception to this is a legal safeguard allowing parties to prevent the use of ISDS for claims applying to tobacco control measures. This is a welcome development. The Australian Government has indicated that it plans to make use of the safeguard. However, new public health policies for alcohol, food labelling, and other measures to protect health and the environment are still potentially open to challenge using the ISDS process.

Box 1: Examples of flawed legal safeguards in the CPA-TPP investment chapter

Investment Chapter Article 9.16: Investment and Environmental, Health and other Regulatory Objectives

"Nothing in this Chapter shall be construed to prevent a Party from adopting, maintaining or enforcing any measure ***otherwise consistent with this Chapter*** that it considers appropriate to ensure that investment activity in its territory is undertaken in a manner sensitive to environmental, health or other regulatory objectives." [emphasis added]

- The phrase "otherwise consistent with this chapter" undermines the safeguard and means that its interpretation can be a matter for dispute in a tribunal.

Investment Chapter Annex 9-B: Expropriation, Article 3(b):
"Non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment, do not constitute indirect expropriations, ***except in rare circumstances.***" [emphasis added]

- The phrase 'except in rare circumstances' leaves a loophole for corporations to argue that their circumstances are rare. This argument was made in a case against Costa Rica over a ban on development in a national park, to protect the nesting grounds of the giant leatherback sea turtle.[14] Regardless of whether such arguments are successful or not, the uncertainty around the language gives investors an opportunity to launch a claim and drag a government through costly litigation.

Earlier leaked drafts of the TPP's investment chapter showed that the Australian Government was attempting to negotiate exemptions from ISDS for specific Australian health programs, including Medicare and the PBS. These exemptions were not agreed to by the other countries and were abandoned in the final CPA-TPP text.

Flaws in the ISDS process

In addition to flawed legal safeguards in the CPA-TPP investment chapter, the investor-state dispute settlement process is a fundamentally flawed and pro-investor system that lacks the safeguards of domestic legal processes.

1) Lack of impartiality and conflict of interest

A report by Corporate Europe Observatory and the Transnational Institute[15] describes how the boom in investment arbitration cases over the last couple of decades has given rise to an elite investment arbitration industry dominated by a small number of investment law firms and arbitrators. Fifteen lawyers were involved in 55 percent of the total international investment cases known up to 2011[16]. Furthermore, the study finds strong ties between this specialised group of investment lawyers that serve on ISDS panels and multinational companies which are the benefactors of the ISDS system. According to this study, investment arbitration lawyers have encouraged governments to sign treaties with poorly worded ISDS clauses that expose them to legal cases, have encouraged corporations to use lawsuits and have actively prevented changes to the investment arbitration system. ISDS investment lawyers often rotate between serving as judges, lawyers for multinational companies, and expert counsel. As *Public Citizen* notes, "there are no meaningful conflict of interest rules with respect to arbitrators' relationships with, or investments in, the corporations whose cases they are deciding"[17]. While Article 9.22.6 of the CPA-TPP allows for the development of a Code of Conduct for arbitrators, this code has not yet been developed and so its merits cannot yet be evaluated. It is unclear to what extent this will address the issues of impartiality and conflicts of interest.

2) No effective review or appeal process

In addition, there is no appeal process for ISDS, meaning the decision of three individuals is binding on governments who have no room for recourse. This further raises the question as to whether small ad hoc ISDS panels "have enough legitimacy to assess the validity of sovereign state law, and de facto restrict the policy choices made by democratically elected legislators"[18]. The Chief Justice of the Australian High Court[19] has cautioned against any potential undermining of the authority of domestic courts by ISDS arbitration.

3) Prohibitive costs

The costs of arbitration under ISDS can be very high. It can cost millions for countries to fight legal claims under ISDS, even if they successfully defend them. The Organisation for Economic Co-operation and Development (OECD) has estimated the costs average more than $8 million per case[20].

The awards involved in ISDS cases are also often very high. The Czech Republic, for example, had to pay more than $350 million USD in an ISDS case, which is reported to have almost doubled its public sector deficit[21]. El Salvador has been sued for over $300 million USD by Pacific Rim, a Canadian gold mining company over its refusal to grant permits for cyanide-based gold mining[22]. In some cases awards have amounted to over a billion dollars.

Regulatory Chill

The threat of legal action, or even the existence of an ISDS mechanism, can deter governments from implementing public health policies and laws. Corporations can also delay the uptake of innovative public health policies and laws in other countries by launching ISDS claims against 'first movers' (the first country to introduce a new approach). Margaret Chan, the Director General of the World Health Organization, has noted that legal actions by tobacco companies have been "deliberately designed to instil fear" in countries trying to reduce smoking.[23] For example, Canada withdrew a proposal for tobacco plain packaging regulation following the threat of ISDS arbitration under NAFTA (Productivity Commission 2010:271) and Uruguay initially decided to weaken its regulations for tobacco labelling after Philip Morris International declared its intention to bring an ISDS claim, before funding was offered by the Bloomberg Foundation to help Uruguay defend the claim.[24]

From a public health perspective, there are no arguments in favour of including ISDS in trade and investment agreements, and the risks to the introduction of innovative public health policies are manifold. For these reasons, PHAA is strongly opposed to the inclusion of investor-state dispute settlement (ISDS) in trade agreements.

Potential effects of the intellectual property chapter on access to affordable medicines

Our 2016 submissions highlighted three concerns arising from the TPP intellectual property (IP) chapter for public health in the Australian context:

a) Ambiguous provisions for biologic medicines which, depending on the interpretation that ultimately prevails, have the potential to significantly impact the cost of medicines for Australians;

b) A range of other provisions that lock in existing IP settings and frustrate future reform efforts; and

c) Potential impact of the IP chapter on access to medicines in developing countries in the region.

Ambiguous biologics provisions

The earlier provisions of the TPP (when it also included the United States as a potential party) biologics have been suspended, but not removed from the CPA-TPP.

Biologic products, which are produced through biological processes, account for a significant and growing share of government expenditure on pharmaceuticals. Biologic products include many new treatments for cancer and immune conditions such as rheumatoid arthritis. They include some of the most expensive medicines on the market, some of which cost hundreds of thousands of dollars per patient per year. The Australian Government spent approximately $2.29 billion dollars subsidising biologic medicines through the Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme in the 2015-2016 financial year.[25]

More than $367 million dollars would have been saved in the 2015-16 financial year alone if biosimilar (follow-on) products had been available.[25] Monopolies on just ten biologic drugs listed on Australia's Pharmaceutical Benefits Scheme cost Australian taxpayers over $205 million in 2013-14.[26]

The United States was seeking 8-12 years of market exclusivity for biologics in the TPP. Battles over the length of monopolies for biologics plagued the TPP negotiations, and proved to be an almost insurmountable stumbling block over the final days.

The Australian Government's brief about the CPA-TPP outcomes for biologics[27] says:

> In the TPP, Australia has negotiated protections that are consistent with Australian law and practice. Australia is not required to change any part of its current law, including data protection for biologics, or our patent regime. There will be no adverse impact on the Pharmaceutical Benefits Scheme and no price increase for medicines.

But the final text of the CPA-TPP's Intellectual Property (IP) Chapter contains some problematic language and troubling ambiguities.[28]

Article 18.51.1 outlines two options that countries can implement to protect new biologics:

1) At least 8 years' protection of clinical trial data (Article 18.51.1(a)); or
2) At least 5 years' protection of clinical trial data along with other measures to "provide effective market protection" and "deliver a comparable outcome in the market" (Article 18.51.1(b))

Whatever the understanding reached between parties in the negotiating room, according to the agreed legal text, it appears that, if the biologics provision were re-introduced, TPP parties are obliged to ensure the same market exclusivity outcomes regardless of which option they choose.

If the biologics provisions are reinstated in the CPA-TPP at a later stage, the legal language provides room for the United States to continue to pressure the other CPA-TPP countries to ensure that they keep biosimilars (more affordable follow-on products) off the market for eight years, in order to provide equivalent "effective market protection" and a "comparable outcome" to eight years of data protection. Following the signing of the original TPP, the US Administration claimed to Congress that the TPP provided eight years of data protection,[29] and some Members of Congress demanded that the period be extended to twelve years before they would be prepared to ratify the CPA-TPP.[30]

In addition, the definition of biologics in the TPP is very broad and likely to limit countries' flexibility in determining the scope of the obligation. A review by the TPP Commission of both the length and scope of protection after ten years provides a further mechanism for US pressure to expand and extend monopolies on expensive biologics.

If the poorly drafted and ambiguous biologics provisions are interpreted in such a way that the Australian Government is not able to bring biosimilars to market in a timely fashion, the CPA-TPP could add substantially to the costs of the Pharmaceutical Benefits Scheme. These costs are likely to be passed on to consumers through higher co-payments, resulting in a financial and health burden for already vulnerable people including those on low incomes, older people, and people with chronic illnesses.

Other CPA-TPP provisions that reduce future policy flexibility to make medicines more affordable

There is a range of prescriptive provisions in the CPA-TPP's intellectual property chapter that would lock in Australia's existing intellectual property settings and reduce the options available for reform. The Draft Report of the Productivity Commission's Inquiry into Australia's Intellectual Property Arrangements[31] found that trade agreements are a significant determinant of Australia's "overly generous" system of intellectual property rights, and constrain domestic flexibility in achieving a more balanced regime:

> While AUSFTA is the only PTA [preferential trade agreement] that has required changes to Australia's IP laws, many of the provisions have been included in subsequent PTAs with countries such as Chile and

> Korea and in the TPP, with some resulting in overlapping and complex rules. As highlighted above, a consequence of embodying so much of our IP provisions in international agreements is that Australia is significantly constrained in reforming its IP arrangements. (p. 470-471; see also p. 2)

The Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines,[32] released in September 2016, was highly critical of the way in which recent trade agreements, including the CPA-TPP, have increased intellectual property protection and enforcement, finding that provisions in the CPA-TPP "significantly reduce the scope of measures that governments can use to pursue public health priorities and fulfil the right to health" (p. 19).

1) Mandatory secondary patents (Article 18.37)

Mandating secondary patents (e.g. patents for new uses and new methods of using existing products) facilitates the practice of pharmaceutical evergreening - in which patent owners extend monopolies by securing additional patents through modifications to existing drugs. Evergreening further delays the entry of generic medicines. A 2013 study of the 15 costliest drugs in Australia found a mean of 49 patents associated with each drug[33]. The Australian Generic Medicines Industry Association has found that delays in the entry of generic competition for 39 PBS listed medicines due to secondary patenting cost taxpayers $37.8 - $48.4 million over a 12 month period (Nov 2011-Nov 2012)[34] [35]. Specifically, researchers have shown that delays to generic entry for the antidepressant venlafaxine (Efexor) due to secondary patenting on modified forms of the drug cost the Australian government $209 million[36]. Similarly, researchers in the US found that secondary patenting on HIV medicines ritonavir and lopinavir/ritonavir could delay generic entry for an additional 19 years beyond the original patent term[37] [38].

While Australian practice currently allows patents for new uses and new methods of a known product, including these provisions in trade agreements would constrain future patent reform in Australia[39].

Paragraph 2 of Article 18.37 (Patentable Subject Matter) – the part of the provision that requires parties to provide secondary patents - has been suspended in the CPA-TPP, but could be re-introduced by parties at any stage unless it is removed.

2) Data protection for small molecule drugs (Article 18.50)

Data protection measures also delay the entry of cheaper generic medicines. While industry claims that data protection is necessary for further research and development (R&D) investment, the Pharmaceutical Patent Review (PPR) found that 'data protection appears to have little impact on the levels of pharmaceutical investment in a country'[40]. There is no evidence that current levels of protection in Australia provide insufficient incentives for investment and the PPR recommended against extending data protection for biologics[41], as the Draft Report from the Productivity Commission's inquiry into Australia's intellectual property arrangements concluded.[31] Studies of data protection measures introduced in Jordan through FTAs showed that in the period 02-06, data protection delayed the introduction of generic medicines for 79 per cent of new medicines[42]. Similarly, assessments of data protection provisions in Guatemala have shown prices for medicines with data protection to be substantially higher[43]. In Thailand, extending market exclusivity for five years was found to increase medicine outlays between 9 and 45 per cent (based on 2002 data)[44].

Data protection has the effect of delaying generic entry and increasing medicine prices. In addition, researchers have pointed out that data protection presents a potential impediment to compulsory licensing – a safeguard that must be protected in FTAs[45]. Delays in generic market entry for PBS listed medicines delay statutory price reductions, costing taxpayers millions of dollars each year[46].

TPP Article 18.50 has been suspended in the CPA-TPP, but could be re-introduced by parties at any stage unless it is removed.

3) Patent term extensions (Articles 18.46 and 18.48)

While Australia currently allows for patent term extensions, which are based on the industry claim that they are required to recoup money for R&D, the independent PPR found that there is no evidence that the costs of extension terms had led to a commensurate increase in R&D[47]. The cost of extensions for PBS drugs during 2012-13 was estimated at $240 million in the medium term and $480 million over the long term[48] [49]. The PPR concluded that Australia should work to reduce the length of patent term extensions. The Draft Report from the Productivity Commission's inquiry into Australia's intellectual property arrangements reinforced these findings and recommended that extensions of term should be more carefully targeted.[31] In addition, researchers have pointed out that the regulatory approval process for the Therapeutic Goods Administration (TGA) is subject to statutory time limits and deduction in fees in case of delays – meaning the granting of extensions for rare delays 'makes little sense'[50].

TPP Articles 18.46 and 18.48 have been suspended in the CPA-TPP but could be re-introduced by parties at any stage, unless they are removed.

4) Patent linkage (Article 18.53)

While several other IP provisions in the original TPP have been suspended in CPA-TPP, the patent linkage provision (Article 18.53) is not. Patent linkage systems involve creating a link between the patent status of the originator product and marketing approval for a generic or biosimilar. The international intellectual property agreement under the World Trade Organization (known as TRIPS) does not include any requirement for patent linkage, but the United States has a patent linkage system and has sought for its introduction in many other countries through obligations included in trade agreements. In the US, patent linkage has been found to be a highly effective strategy for originator pharmaceutical companies to "protect existing high value drug products from generic competition".[51]

Australia already has a form of patent linkage that was introduced due to the Australia-US Free Trade Agreement. The TPP patent linkage provisions, retained in the CPA-TPP, would not require Australia to change its system. However, these provisions would create another layer of international obligations that would 'lock in' a system which has been strongly criticised by the Australian generic medicines industry.[52] Generic pharmaceutical companies seeking marketing approval for their products must first go through a process to identify any patents that may apply; a process that is very burdensome and has a high degree of uncertainty due to the opacity of the Australian Register of Patents and the difficulty of identifying all the patents that might apply to a particular medicine. They must then certify either that they will not market the product in a manner that infringes a valid patent or that they have notified the patent holder that they plan to market the product before the end of the patent. Criminal penalties apply for providing false or misleading certificates. This creates a significant barrier to the market entry of generic and biosimilar medicines, with implications both for the generic medicines industry and for government expenditure on pharmaceuticals.

Access to medicines in developing countries

Doctors Without Borders/Médecins Sans Frontières (MSF) has repeatedly warned that the TPP could be disastrous for access to medicines in developing countries. At the conclusion of the negotiations, MSF issued a statement including the following comment:[53]

> MSF remains gravely concerned about the effects that the Trans-Pacific Partnership trade deal will have on access to affordable medicines for millions of people, if it is enacted. Today's official release of the agreed TPP text confirms that the deal will further delay price-lowering generic competition by extending and strengthening monopoly market protections for pharmaceutical companies.

Gleeson et al[54] examined six provisions in the original TPP which extend or expand exclusivities on medicines:

- Article 18.37.2 – patents for new uses, new methods or new processes of using an existing product;
- Article 18.46 and 18.48 – patent term extensions to compensate for delays in granting patents and delays in marketing approval;
- Article 18.50 – exclusivity for undisclosed test data for small molecule drugs;
- Article 18.51 – exclusivity for undisclosed test data for biologics; and
- Article 18.53 – patent linkage.

This was not an exhaustive list, but focused on the provisions which were most likely to impede access to affordable medicines. Gleeson et al[54] showed that the developing countries involved in the agreement (particularly Brunei Darussalam, Malaysia, Mexico, Peru and Vietnam) would need to introduce far more changes to their domestic laws than the developed countries if the TPP were adopted in its original form.

Most of these provisions have now been suspended, with the exception of Article 18.53 (patent linkage). Gleeson et al found that legislative change will likely be necessary for Brunei Darussalam, Malaysia and Vietnam to introduce patent linkage systems. These countries are provided with only short transition periods in the TPP/CPA-TPP: 3 years, 4.5 years and 3 years respectively. It is worth noting that patent linkage originated in the United States and the US remains the only country that seeks to introduce patent linkage system through its trade agreements.

The TPP IP chapter also included a number of enforcement provisions which have been incorporated into the CPA-TPP. While earlier drafts of these provisions were analysed, there is no published analysis of the final text for these provisions and their likely effects on developing countries. This is an area where further study is needed.

Lack of effective environment protection

The natural environment is a determinant of health because of the ecosystem functions which underpin the development and maintenance of human civilisation. PHAA has two major areas of concern for the environment arising from the CPA-TPP.

The primary concern for the environment is the potential use of the ISDS mechanism to limit or subvert government action to protect the natural and built environments. By 2012, 32 ISDS cases involving environmental issue had been initiated. Of these, two were settled in favour of the country with payouts of three and 7.5 million US dollars by corporations, and seven in favour of the company who brought the action. The mean determination was US$25.6 million (ranging from two to 122 million US dollars; median US$ 13 million), which is prohibitively expensive for small nations. The magnitude of claims for damages ranged from US$5.6 million to US$13.5 billion.[55] The costs and aggravation for countries of managing an ISDS case may engender 'regulatory chill' wherein environmental and health protection regulation is not undertaken.

The types of government action that corporations and companies have sought damages over include: clean-up of contaminated industrial and mine sites, regulating chemical additives to fuel, regulating hunting and fishing, maintaining or expanding biodiversity and conservation areas, appealing compensation for environmental damages awards, changing the regulatory environment or imposing more stringent environmental requirements.[55]

One example to illustrate this: In 2008 the El Salvador government attempted to protect the quality of their water supply from the effects of cyanide based gold mining by American based Pac Rim Cayman. Pac Rim Cayman began proceedings, but they sold the lease and the case to Australian company OceanaGold.

OceanaGold is seeking US$300 million in compensation for lost income from the Salvadoran government, unless mining is permitted to proceed.

The second area of concern is the failure to recognise current environmental treaties and obligations, and where these are mentioned the language is weak and the requirements insufficient to enforce or adequately protect their intent. Where mention is made, rules in other chapters allow the environmental safeguards to be transgressed. The current weak enforcement mechanisms which have consistently failed to curb environmental violations are carried across into the CPA-TPP.[56]

The CPA-TPP environment chapter fails to even mention climate change, or the United Nations Framework Convention on Climate Change (UNFCCC), and fails to require CPA-TPP countries to adhere to their UNFCCC commitments despite the fact that all CPA-TPP countries are party to the climate convention.

Further, the environment chapter offers no protection from CPA-TPP rules that would allow foreign investors and governments to challenge climate and clean energy policies in unaccountable trade tribunals. The environment chapter includes no safeguards for green jobs programs that could run afoul of the TPP's procurement rules, fossil fuel export restrictions that could violate CPA-TPP rules on trade in goods, energy-saving labels that could be construed under the TPP as "technical barriers to trade," border adjustment mechanisms that could conflict with CPA-TPP rules despite boosting the efficacy of domestic greenhouse gas mitigation, or an array of climate change policies that could be challenged by foreign fossil fuel corporations as violations of the CPA-TPP's special rights for foreign investors. With no protection for such policies from the CPA-TPP's polluter-friendly rules, the TPP could not only spur increased climate-disrupting emissions, but inhibit domestic efforts to curb such emissions.

The state-state dispute settlement mechanism for environmental provisions in all US trade agreements since 2007 has failed to produce a single formal case against documented environmental violations. The final TPP environment text largely replicates the old, ineffective mechanism.

Alcohol health warning labels

The evidence on health warning labels indicates that health warnings are most likely to be effective if they are mandatory, large, placed on the front of a container and including both graphic and text elements.[57] While the TPP does not expressly prevent Australia or other CPA-TPP countries from introducing health warning labels for alcoholic beverages, it does include provisions that may be used to frustrate efforts to introduce such evidence-based health warnings. [58,59]

A special annex to the CPA-TPP Technical Barriers to Trade Chapter applying to wine and distilled spirits (Annex 8-A) allows suppliers of these products to provide information required by the importing country (such as health information) on a supplementary label. While there is no definition of a supplementary label, it is generally understood to be a label that is added to the container in addition to the standard labelling.

A CPA-TPP country introducing a requirement that warning labels be displayed on the main label(s) on an alcohol container or that large health warnings be displayed on the front of a container may face an argument that it has breached the obligations of the Agreement. Such an argument might be made by another CPA-TPP party (using the state-state dispute settlement process) or an alcohol industry corporation (using the ISDS mechanism). Exceptions and legal safeguards incorporated into the CPA-TPP would assist in defending such a claim. However, such a claim might still be made in the hope of deterring governments from proceeding with health-related labelling measures.[58,59]

Experts have recommended that the alcohol labelling rules in the TPP be amended to exclude information about human health, or at least to affirm that states can prescribe how and where health information is

presented on wine and spirits containers.[58] However, such amendments have not been included in the CPA-TPP.

The Need for a Comprehensive Health Impact Assessment of the final CPA-TPP text

Health impact assessment (HIA) is a systematic process that considers the potential health effects of a proposed policy, plan, or project, and offers recommendations to mitigate health harms and improve benefits.[60] HIAs have been used widely in countries such as Australia, the UK and the US to inform decisions in a wide range of sectors, such as transportation, resource extraction, health services and energy development. A recent evaluation of HIA in Australia and New Zealand found that HIAs have been useful at informing, changing, or influencing decisions to better integrate health.[61] Guidance from the World Health Organization explicitly calls for the use of HIA to better integrate health into various policy decisions, particularly those that affect the social, economic, and environmental determinants of health.[60]

Recently, HIA has been explored as a tool to inform the development of free trade agreements. A group of Australian health organisations, including PHAA, conducted an HIA of the TPP during its negotiation, prior to release of the final text.[62] The HIA relied on leaked drafts of the text, along with consideration of previous trade agreements and consultation with experts, to determine the potential health effects of various provisions included in the draft agreement. Specifically, the HIA considered the potential impacts to health in the areas of the cost of medicines, and the ability of Government to regulate alcohol, tobacco, and food.

The HIA identified concerns related to regulation of alcohol control, tobacco control, and food labelling (potential impacts to the cost of medicines have been discussed in other parts of this submission). The HIA found that the technical barriers to trade chapter, the wine and spirits annex, and the intellectual property chapter may make it more difficult for Australia to implement innovative control measures, such as health warning labels on alcohol containers, particularly where the evidence base for the intervention is still developing.

Similarly, rules in the technical barriers to trade chapter may limit future legislation for food labelling. The regulatory coherence and transparency chapters could also enable a greater role of the processed food industry in policymaking, which may influence the food labelling system used in the future.

Despite a carve-out of tobacco from ISDS in the final agreement, the HIA identified provisions in other chapters such as the technical barriers to trade chapter which may affect tobacco regulation and distribution. The ISDS carve-out also only applies to tobacco, leaving domestic regulation of alcohol and food labelling vulnerable to challenge from international corporations.

The HIA recommended several measures to modify the draft text in order to mitigate these potential threats to health. These included excluding ISDS from the trade agreement, or if it was included, to incorporate safeguards that would prevent investors from making claims related to public health policies. A full discussion of the findings and recommendations is included in the final HIA report.[62 63]

While some of the provisions proposed for the TPP were mitigated or removed during its negotiation, many still remain in the final text, and many of these also remain in the CPA-TPP. These need careful scrutiny by teams of experts, along with evidence-informed public debate.

It is important to note that while the findings and recommendations of the HIA provide important insight for the potential health outcomes of the TPP, they are limited by the fact that the HIA was conducted prior to release of the final text. Therefore, in order to more specifically determine the outcomes of the final text and provide recommendations, a comprehensive HIA should be conducted on the final text, while the CPA-TPP is still being considered by Parliament.

Conclusion

While some of the concerns raised by PHAA were addressed during the negotiation of the TPP, and a small number of problematic provisions have now been suspended following the withdrawal of the US, many problems for public health still remain in the final CPA-TPP text. These include:

- The inclusion of an investor-state dispute settlement (ISDS) mechanism, which lacks safeguards that are guaranteed to prevent the use of ISDS against legitimate public health and environmental policies (except with respect to tobacco control measures).
- Intellectual property provisions that hamper access to affordable medicines, particularly the ambiguous biologics provisions which hold significant risks for Australians, along with a range of other provisions that reduce policy flexibility to reform our intellectual policy settings in the future. While many of these provisions have now been suspended, they may be reinstated at a later stage. Provisions remain in the CPA-TPP that would affect access to medicines in developing countries.
- Weak environmental protections which, coupled with the ISDS mechanism, are likely to undermine efforts to address key environmental challenges, including climate change.
- Provisions that have the potential to be used to deter parties from introducing evidence-based alcohol policies, including mandatory alcohol health warnings.

This is by no means an exhaustive list: PHAA does not have sufficient resources to conduct a full Health Impact Assessment on the final text.

The Productivity Commission Trade and Assistance Review 2013-14 found that "the complexity of bilateral and regional trade agreements and the potential for provisions to impose net costs on the community presents a compelling case for the negotiated text of an agreement to be comprehensively analysed well before signing". Our initial analysis of the CPA-TPP text suggests that there is grounds for ongoing concern about the potential impact of the CPA-TPP on public health and that such comprehensive analysis of the final text is both justified and necessary.

PHAA recommends that the CPA-TPP should not be ratified by the Australian Parliament until a comprehensive, independent health impact assessment is conducted.

The PHAA appreciates the opportunity to make this submission and would be happy to elaborate on the views expressed at a future public hearing. Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

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10 September 2018

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